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Dedicated to protecting and improving the health and environment of the people of Colorado

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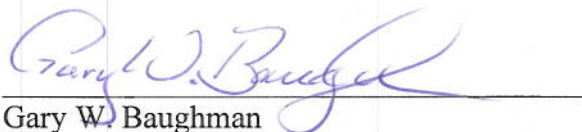
COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

HAZARDOUS MATERIALS AND WASTE MANAGEMENT DIVISION


RADIATION PROGRAM

ENFORCEMENT RESPONSE POLICY

The Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division will use the attached policy, in evaluating enforcement options that are appropriate for addressing violations of radiation management laws and regulations in Colorado.



Gary W. Baughman
Division Director



Date

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
HAZARDOUS MATERIALS AND WASTE MANAGEMENT DIVISION

RADIATION PROGRAM

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I. Introduction

The goal of the Radiation Program is to ensure users of radioactive materials and radiation producing machines maintain a high level of compliance with the requirements of the Radiation Control Act, at sections 25-11-101, C.R.S. through 25-11-305, C.R.S., (“the Act”) and the State of Colorado *Rules and Regulations Pertaining to Radiation Control* (“the Regulations”), at 6 CCR 1007-1. Compliance is achieved through a continuing process that includes communication to define the regulatory expectations and requirements, and evaluation of the regulated entities’ compliance. Communication of expectations is accomplished through understandable and accessible regulations, guidance, licensing, and registration processes. Compliance evaluation is accomplished through inspection and enforcement, which further communicates the Department expectations.

A timely, visible and effective enforcement action along with an engaged and cooperative effort by the regulated entity will return the facility to compliance as expeditiously as possible, as well as deter future non-compliance (violation), both at the subject facility as well as at other facilities. This *Radiation Program Enforcement Response Policy* provides a general framework for how violations and other findings are evaluated and ultimately dispositioned to ensure a return to compliance. This Enforcement Response Policy describes mechanisms for enforcement to address non-compliant facilities. Non-compliant facilities are those regulated entities which have failed to properly or fully implement the requirements of the Regulations or requirements of the registration pertaining to radiation machines, or the radioactive materials license.

This Enforcement Response Policy does not address violations determined to be potentially criminal in nature and which are being investigated and prosecuted pursuant to State criminal authorities.

The policies and procedures set out in this document are intended solely for the guidance of Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division (“the Division”) personnel. They are not intended and cannot be relied upon to create rights, substantive or procedural, enforceable by any person party in litigation with the Division. The Division reserves the right to be at variance with this policy. The Division also reserves the right to change this policy at any time with appropriate publication. This revision addresses changes to the Radiation Control Act instituted in 2010 that impact the enforcement process.

II. Program Structure

The Radiation Program consists of two primary regulatory elements: the Radioactive Materials Unit, and the X-Ray Certification Unit. The Radioactive Materials Unit regulates the acquisition, use and disposal of radioactive materials. The X-Ray Certification Unit regulates the use, inspection and servicing radiation producing machines. These programs are largely prevention-oriented and regulate through a system of regulations, licensing and registration processes and documents, and through performance of compliance inspections. Regulations are found at 6 CCR 1007-1, the Rules and Regulations Pertaining to Radiation Control. Radioactive material licensing activities are described in licensing process documents and compliance activities are performed in accordance with Radioactive Materials Unit internal compliance procedures. The procedures identify inspection activities, requirements and methods. The X-Ray Certification Unit also utilizes internal procedures which address inspection activities, requirements, and methods applicable to radiation producing machines.

III. Compliance Inspection Process

Compliance inspections are performed on a periodic basis at a frequency related to the health and safety risk presented by use of the radioactive materials or radiation machines, and are dictated by the Regulations, Federal requirements and other nationally accepted guidance and standards. Inspections may be announced or unannounced. Due to the structure of the Colorado Radiation Program, the compliance process differs somewhat between the Radioactive Materials Unit and the X-Ray Certification Unit, as outlined below.

RADIOACTIVE MATERIALS UNIT

Routine inspections of Radioactive Materials licensees are performed by Radioactive Materials Unit Inspectors. Non-routine inspections may also be conducted at the discretion of the Unit as a result of an incident, allegation, or other initiating event. Once an inspection is completed, a "Compliance Inspection Report, RCD 59 Form" (59 Form) or Notice of Violation ("NOV") letter are issued to the licensee/entity. Inspectors may issue a 59 Form in the field at the end of the inspection if there are just a few (less than six) items of non-compliance. Inspections resulting in six or more violations or violations that are complex are typically handled through issuance of an NOV letter and may result in escalated enforcement actions.

X-RAY CERTIFICATION UNIT

Inspections conducted under the X-Ray Certification Unit are categorized as routine and non-routine. Routine inspections of radiation producing machine registrants are conducted by privatized, registered Qualified Inspectors (QI's). Qualified Inspectors will issue a 59-1 Form for machine violations or a 59-2 Form for facility violations. Machine violations are regulatory violations related to the failure or improper operability of a radiation producing machine and associated systems within specified parameters or requirements. Facility violations are regulatory violations not related to machine performance and are issued only when such violations are found. Upon completion of the inspection, the facility, the QI and the Division receive copies of the 59 forms. Part 2 of the Regulations and the 59 Form instructions establish specific timeline requirements for distribution and submission of 59 Forms and related reports to the Division.

Non-routine inspections of registrants are performed by CDPHE Staff Inspectors based on the specific inspection findings of a QI, a complaint or allegation, data generated from the registrant database, or other information. Staff Inspectors may initiate a non-routine inspection if it is determined that a violation discovered by a QI or other mechanism exists and further enforcement action is warranted. Violations issued by a QI do not initiate the thirty (30) day time period for escalated enforcement as described in the Act – only a Notice of Violation issued by the Division will initiate the escalated enforcement “clock”. Staff Inspectors issue non-routine inspection findings through a NOV Letter. Registrants that fail to respond to a violation cited in a 59-1 or a 59-2 inspection report issued by a QI, may be issued a NOV letter.

Staff Inspectors also perform non-routine inspections of QI's, QE's (Qualified Experts, as defined in Part 1 of the Regulations), and registered service companies to ensure that they are in compliance with the Regulations. The enforcement process for these entities will follow a process similar to that for other types of end user registrants.

Licensees, registrants, QI's, and Service Companies may be subject to hourly or flat rate fees for non-routine inspections (including re-inspections) as provided by Part 12 of the Colorado Rules and Regulations Pertaining to Radiation Control. These fees are not penalties and are separate from and in addition to any administrative penalty that may be issued as part of an escalated enforcement action against a regulated entity.

Regardless of which Unit conducts the inspection process - X-Ray Certification, or Radioactive Materials – the Division shall issue, within a reasonable time, a written notice of the violation(s) specifying:

- (I) The factual basis of each act or omission with which the person is charged; and
- (II) The particular provision of the statute, rule, order, license, or registration certificate violated.

A 59 Form or Notice of Violation letter are the formal notification mechanisms used and are issued for all cases of non-compliance regardless of the significance or severity of violations discovered at a facility. An enforcement action initiated through issuance of a Notice of Violation, notifies a facility of its lack of compliance and lists actions to be taken to mitigate that non-compliance. The NOV is an enforcement action that is binding upon the facility and is considered an enforceable instrument. All inspection findings are documented in the inspection report, and reviewed by the inspection lead and/or Unit leader. The NOV may also identify one or more items of concern, or recommendations. An item of concern is not a violation, but has health and safety significance that could lead to noncompliance if left uncorrected. A recommendation is a suggestion of a good practice with no health and safety implication or regulatory requirement.

An NOV Letter is issued in lieu of the 59 Form when there are a significant number of violations identified or the violations are complicated or more severe. As soon as possible following the inspection, the authorized inspector should issue the NOV letter in consultation with their Inspection Lead or Unit Leader. The NOV serves several purposes, and provides a facility with notice of the following:

- a) the deficiencies that the inspector believes are violations of the Act, license, registration and/or the Regulations;

- b) areas of the compliance inspection that are unresolved or have not been completed, and are still being evaluated;
- c) required submittals and/or corrective actions, with a time frame for completion of these objectives (where applicable);
- d) items of concern which the inspector believes might either be violation(s) of other environmental laws or that may lead to violation of radiation management laws;
- e) informs the facility of the Division's process to reach resolution of the alleged violations and outstanding issues;
- f) informs the facility of its right to request an informal conference with the Division; and
- g) informs the facility of the consequences for continued non-compliance.

The 59 Form and NOV letter requires certain actions be completed by the regulated entity and the Division within certain time constraints. These timelines are outlined in later sections of this policy.

Notice of Violation items involving significant and/or numerous violations or repeat violations are handled through an escalated enforcement process as outlined in later sections of this policy.

If no violations are found during the inspection, a "clear" 59 form is issued to the regulated entity indicating that no violations were observed or noted during the inspection. Unless otherwise indicated on the form or where non-violation items of concern or recommendations require a response, the compliance process is complete and no further action is required on the part of the regulated entity.

IV. Determination of Appropriate Enforcement Response

Once it is determined that violations have occurred, Radiation Program staff and management evaluate the inspection findings, the regulated entities' information and data presented in response to the NOV, and the compliance history of the violator to determine whether the violations will be addressed through routine (non-escalated) enforcement mechanisms, or that they are significant enough to warrant further action through an escalated enforcement process. The selection of the appropriate enforcement response is an integral component of the Radiation Program's enforcement process. The nature of the violations and the good faith response of the facility will likely determine the path forward for resolution of the issues raised in the Notice of Violation.

The decision whether to use escalated enforcement actions for any particular violation will be based upon the following guidelines:

- 1) evaluation of data gathered during the inspection, and the information presented by the violator;
- 2) the Severity Level¹ of the violation and risk to public health and safety and the environment;
- 3) the past compliance history of the regulated entity;
- 3) if the licensee/registrant has failed to respond to a past notice of Violation or has repetitive violations;
- 4) if the licensee/registrant is recalcitrant or has chronic, or widespread Severity Level IV violations; or

- 5) if the time frame for returning to compliance is unreasonably long.

¹Severity Levels are used as a tool to rank the relative significance and impact of different violations once the Department has evaluated the available information. Example violations are categorized by Severity Level in Appendix A of the Radiation Program Penalty Policy, as Severity Level I through V. Severity Level I violations receive the highest priority for enforcement. Severity Level I, II, and III violations will be subject to an escalated enforcement response and receive the strongest appropriate enforcement response. Severity Level IV and V violations involve public health, worker safety or environmental items of lower significance, and do not typically result in escalated enforcement actions but are handled through routine/non-escalated enforcement mechanisms.

Chronic non-compliance with the requirements may be construed as disregard for the regulatory program and will not be tolerated. Compliance should be achieved as quickly as possible and the violator shall be made aware of which requirements need to be met. Escalated enforcement may be appropriate if a violator fails to meet the requirements of a notice of violation.

V. Non-Escalated Enforcement

Historically, the majority of enforcement actions are processed through routine, non-escalated enforcement processes. Once a NOV is issued, the regulated entity is required to provide additional information and data in response to the Division in accordance with the timelines herein. The regulated entity is afforded the opportunity to meet with the Division through an informal conference to provide additional data, arguments, or information regarding the NOV. After consideration of any written response and informal conference, the Division shall issue a letter, within thirty days after the date of the informal conference or the receipt of a written response, whichever is later, affirming or dismissing the violation(s). Items which are not fully addressed by the registrant/licensee in their response will be handled through additional formal correspondence between the regulated entity and the Division until the matter is resolved.

VI. Escalated Enforcement

An escalated enforcement action is an action that further mandates compliance through non-routine mechanisms. The initial sequence of events, actions, and timelines following an inspection is generally the same for non-escalated and escalated enforcement, except where there exists a significant and immediate threat to public health. In those instances of substantial threat to human health, safety, or the environment, the Division will take immediate escalated enforcement actions to establish or restore safe conditions which may go beyond those specified in this policy.

Once it is determined that the violation(s) issued to a regulated entity warrant escalated enforcement, escalated enforcement actions are initiated. The Radiation Program has the ability to impose escalated enforcement actions when it is deemed that the licensee or registrant has numerous violations, repeated violations, or where there has been a significant breakdown in operations or management that could affect compliance or overall health and safety. Escalated enforcement actions will also address liability for penalties. The *Radiation Program Penalty Policy* describes the process for determining the amount of penalties in accordance with

requirements of the Act.

Escalated enforcement actions, which are described in further detail below include:

- a) issuance of a Unilateral Compliance Order;
- b) issuance of a Compliance Order on Consent;
- c) issuance of a Judicial Order;
- d) issuance of a Cease-and-Desist order; and
- e) suspension, revocation, or termination of a license or registration.

A Unilateral Compliance Order issued pursuant to section 25-11-107(5)(d), C.R.S. will be issued to the registrant or licensee following the time allowed for a written response to the NOV and informal conference. At a minimum, Unilateral Compliance Orders will include the following:

- a) the findings of fact and conclusions of law for each cited violation;
- b) a list of requirements designed to bring the facility back into compliance, including schedules for completion;
- c) notice of the effective date of the Order;
- d) notice of the facility's liability for penalties; and
- e) instructions for requesting a hearing to discuss the findings and requirements in the Order.

In cases where penalties are to be levied and a Unilateral Compliance Order is used, an Assessment of Administrative Penalty letter, along with the Order will be issued as specified in 25-11-107(5)(c), C.R.S. The Unilateral Compliance Order directs the recipient to pay the penalty amount. Within thirty (30) days of receipt of the Order, the recipient can request a formal hearing contesting the violation or penalty, as specified in 25-11-107(5), C.R.S.

Pursuant to section 25-11-103(5), C.R.S., Unilateral Compliance Orders may also be issued in the event of an emergency relating to any source of ionizing radiation, which endangers the public peace, health or safety. The Radiation Program may also invoke the authorities under Sections 25-1-109(1), C.R.S. and 25-1.5-101(1)(l), C.R.S. to establish and enforce standards for exposure to environmental conditions, including radiation, that may be deemed necessary for the protection of public health.

A Compliance Order on Consent is a negotiated document setting forth agreements reached between the Division and facility representatives. At a minimum, a Compliance Order on Consent will include the following:

- a) a list of the alleged violations;
- b) a list of requirements designed to bring the facility back into compliance, including schedules for completion;
- c) notice of the effective date of the Order on Consent;
- d) agreements made to settle any penalty claims the Division may have against the facility.

In cases where penalties are to be levied and a Compliance Order on Consent is used, a transmittal letter, along with the Order in draft form will be sent to the recipient. The cover letter transmitting the Order on Consent will direct the recipient to review the Order and the recipient may request a settlement meeting to discuss and review the Order, discuss the settlement of

proposed penalties and required corrective actions. Within one-hundred-eighty (180) days of the meeting, the final Order on Consent will be signed by the Division and recipient.

A Judicial Order is issued by a court of competent jurisdiction upon the Division's request that the Attorney General's Office bring a civil action against a licensee or registrant. Civil actions brought under the Act, license, registration, and/or the Regulations will likely request both injunctive relief and monetary penalties.

A Cease-and-Desist Order is issued by a court of competent jurisdiction upon the Division's request pursuant to 25-11-107(7), C.R.S. that the Attorney General's Office bring action against a licensee or registrant to cease operations involving sources of radiation. The cease-and-desist order shall set forth the provision alleged to be violated, the facts alleged to constitute the violation, and the time by which the violation must cease.

Suspension, revocation, or termination of a license or registration may also be initiated. In such instances the Radiation Program will notify the licensee or registrant that their registration or license authorizing use of radiation producing devices or radioactive materials has been suspended, revoked, or terminated. For radiation machine registrants, this will be initiated through formal written notice from the Division to the registrant and may also involve placement of an "unsafe for use" label on the radiation device. For radioactive materials licensees, this action will be initiated through formal written notice from the Division and issuance of an amended license indicating use of materials is suspended or revoked, or that the license is otherwise terminated.

VII. Timeline for Enforcement Actions

Response time guidelines for non-escalated, and escalated enforcement actions are designed to address the issues surrounding the violation and expeditiously return non-compliant entities to compliance with all applicable radiation control rules and regulations. While recognizing that case specific circumstances may dictate exceeding the response time guidelines, every effort should be made to adhere to the guidelines set forth below.

Once the inspector has determined that violations have likely occurred, a Notice of Violation:

- a) will be issued by the inspector in the field at the time of the inspection (59 Form issued by the Radioactive Materials Unit staff only); -OR- issued via formal letter that must be sent to the licensee/registrant by certified mail with return receipt requested (NOV letter); and
- b) shall describe the violation(s) and reference the statute, regulation, license condition, or registration requirement that has been violated;
- c) shall inform the licensee/registrant of the opportunity that they have fifteen (15) days from receipt of the NOV to request an informal conference with the Division to discuss the violations and allow the regulated entity to present additional information. The informal conference is to be held within thirty (30) days of the facility's receipt of the NOV; and
- d) shall inform the licensee that they have thirty (30) days from their receipt of the NOV to submit a written response that:

- i. identifies corrective actions taken to address the violations, items of concern and recommendations; and
- ii. the date when full compliance will be achieved.

The informal conference described in item “c” above provides an opportunity for the regulated entity to discuss the violations alleged in the NOV and pose any outstanding questions, and/or present information to the Division in response to the issues raised in the NOV.

After consideration of any written response and informal conference with the regulated entity, the Division shall issue a letter, within thirty (30) days after the date of the informal conference or the receipt of a written response, whichever is later, affirming or dismissing the violation(s). Any remaining corrective measures that are necessary, and any administrative penalty determined to be appropriate, will be incorporated into an administrative order through the escalated enforcement process.

VIII. Timeline for Escalated Enforcement Actions

Although the initial actions and timelines are generally the same for non-escalated and escalated enforcement activities, escalated enforcement actions follow more rigorous schedules beyond the NOV, as defined by the Act and the Regulations. An “evaluation date” will be established and will be defined as the date when enforcement personnel decide that a higher “escalated” level of enforcement response is appropriate. Every effort should be made to meet the following timelines for the evaluation date:

- 1) if a Notice of Violation has been issued, the evaluation date should be within thirty (30) days of the issuance of the Notice of Violation; **or**
- 2) if an Informal Conference is held regarding an issued Notice of Violation, the evaluation date should be within thirty (30) days of the Informal Conference.

Target response times are established for Unilateral Compliance Orders, Compliance Orders on Consent, and referrals to the Attorney General’s Office for commencement of Civil Actions/Judicial Orders as follows:

- 1) Unilateral Compliance Orders issued pursuant to section 25-11-107(5)(d), C.R.S. will be issued following the time allowed for a written response to the Notice of Violation and informal conference.
- 2) Compliance Orders on Consent should be fully executed within one hundred eighty (180) days from the evaluation date.
- 3) Civil Actions, Judicial Orders, or Cease-and-Desist Orders should commence within forty-five (45) days from the evaluation date.

If the circumstances warrant, the Division shall issue an order containing the elements of both the Notice of Violation specified in paragraph (5)(b) of 25-11-107, C.R.S., and the letter described in section 25-11-107(5)(c)(IV), C.R.S. The decision letter and the order shall notify the alleged violator of the right within thirty (30) days to request a hearing held in accordance with section 24-4-105, C.R.S., to determine:

- (a) whether the alleged violation exists or did exist;
- (b) the reasonableness of the time set for corrective action; and

(c) whether the administrative penalty is reasonable in light of the statutory criteria on which it is based.

The violator shall address each violation in the order and specify what is being appealed. An allegation not addressed in the request for the hearing shall be deemed admitted, and penalty amounts, as applicable to those items shall stand.

Target response times for suspension, revocation, or termination of the license or registration will be determined by the Radiation Program on a case-by-case basis, but should not exceed forty-five (45) days following issuance of the NOV.

The final action of the Division is subject to judicial review pursuant to section 24-4-106, C.R.S.